K131289

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

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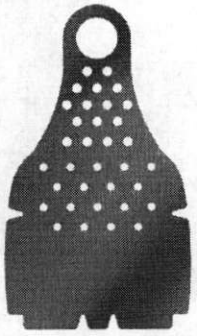
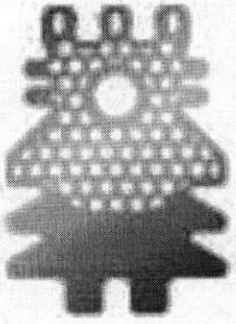
Device Information:
Device Name: i-Gen
Common Name: Plate, Bone
Regulation number: 21 CFR 872.4760
Classification Name: Bone Plate
Product Code: JEY
Classification: Class II
Date Prepared: 8/23/2013

SEP 25 2013

General Description
i-Gen is 3D Pre-Formed titanium membranes. This Titanium membrane is intended for stabilizing and supporting bone graft in dento-alveolar bony defect sites. The devices are made of CP Ti Grade 2 (ASTM F67) and supplied in various sizes and shapes, non-coated, sterile, for single-use and disposable. i-Gen can be chosen according to the size and shape of bone defect. It has seven kind of buccal widths (9, 10, 11, 13, 15, 17, 22 mm) and four kind of buccal lengths (11, 15, 16, 17.5 mm). It has also four types (A B, C, D type), and three sizes (Small, Regular, Wide) for each type according to the location of the part used.

Indication for use
i-Gen is a titanium bone plate device intended to stabilization and support bone grafts in dento-alveolar bony defect sites.

Predicate devices
neobiotech Neo Titanium mesh (K111761)

	Subject Device	Predicate Device
510(k) Number	Not available yet	K111761
Device Name	i-Gen	Neo Titanium mesh (CTi-mem)
Manufacturer	Megagen Implant Co., Ltd.	neobiotech Co., Ltd.
Indications for Use	To stabilization and support bone grafts in dento-alveolar bony defect sites	To stabilize and support of bone graft in dento-alveolar bony defect sites
Design		
Material	CP Titanium Grade 2 (ASTM F67)	CP Titanium Grade 2 (ASTM F67)
Sterilization	Sterile	Sterile
Width	9, 10, 11, 13, 15, 17, 22 mm	8, 9, 10, 12 mm
Length	11, 15, 16, 17.5 mm	6, 8, 10, 15, 20 mm
Product Code	JEY	JEY
Shelf life	5years	-
SE	i-Gen has same device characteristics, material, and intended use as the predicate device, such as the Neo Titanium mesh.	

Substantial Equivalence Comparison

i-Gen has a substantially equivalent in intended use and device characteristics as the predicate device, such as the Neo Titanium mesh. The subject and predicate device are similar in size and materials. When compared with predicate device, no new questions of safety or effectiveness have been raised for i-Gen.

Non-Clinical Test Data

The biocompatibility testing such as cytotoxicity in accordance with ISO 10993-5, sterilization validation, and shelf life validation were performed on this subject device.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Megagen Co., Ltd. concludes that i-Gen is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Megagen Implant Company, Limited
C/O Ms. April Lee
Consultant
Kodent
325 North Puente Street Unit B
BREA CA 92821

Re: K131289
Trade/Device Name: i-Gen
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 23, 2013
Received: August 27, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

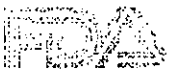
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


Richard C. Chapman for

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K131289

Device Name: i-Gen

Indications for Use:

i-Gen is a titanium bone plate device intended to stabilization and support bone grafts in dento-alveolar bony defect sites.

Prescription Use _____X_____ **AND/OR OverThe-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.09.24 14:43:14 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131289